

K131383

Advanced Brain Monitoring, Inc. X-Series System

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: November 26, 2013

SUBMITTER:

Advanced Brain Monitoring
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008
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NOV 27 2013

PRIMARY CONTACT PERSON:

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Member
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Dan Levendowski
President and Co-founder
Advanced Brain Monitoring, Inc.

DEVICE:

TRADE NAME: X-Series System

COMMON/USUAL NAME: X10 / X24

CLASSIFICATION NAMES: 882.1400 Electroencephalograph

PRODUCT CODE: GWQ, OMC

PREDICATE DEVICE(S):

K130013 X4 System

DEVICE DESCRIPTION:

The X-Series System is indicated for acquiring, transmitting, displaying and storing physiological data in patients. It can be used with ambulatory patients in the home, health care facility, or clinical research environment. The X-Series system requires operation by a trained technician.

The X-Series System is comprised the X10 and X24 Headsets and accessories, Synapse Cream, X-Series Basic Software and BT receiving unit. The X-Series Basic Software is also compatible with the Models X4-E, and X4-M (K130013) when used in wireless mode.

The X-Series System combines hardware, firmware and software to acquire physiological signals. It acquires physiological data through a battery powered headset worn by the patient and provides a flexible platform for applying sensors using synapse cream and acquiring signals from multiple locations on the head or body, transmitting and recording the signals and providing visual indications to ensure high quality data are obtained.

Model X24 provides for acquisition of twenty channels of electroencephalography (EEG) and four optional channels connected to two sensors via a dual-lead connector. Model X10 provides for acquisition of nine channels of electroencephalography (EEG) and an optional channel connected to two sensors via a dual-lead connector. Both models measure movement and position measured via a 3-D accelerometer. The device is designed so it can be affixed by a technician and displays the signals via a wireless connection during acquisition. The X-Series Basic software monitors signal quality to ensure that the sensors are properly applied and that high quality signals are being acquired.

The X-Series Basic software provides a means to: a) initiate a study and track patient information, b) acquire and wirelessly transmit signals from the device, c) visually inspect the signal quality.

The acquired signals are saved in a universal data format (European Data Format Plus, EDF+) that is intended to be analyzed by a Physician using FDA cleared third party software, i.e. Persyst Software (K011397).

INTENDED USE:

The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals. The X-Series System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

Advanced Brain Monitoring, Inc. X-Series System

TECHNOLOGY:

The X-Series System uses the same fundamental technology as the X4 System for most features including the electrophysiological (EEG, EOG, ECG, EMG,), wireless acquisition, and actigraphy. The technologies used in the X-Series are used in the same manner as the predicate products and do not raise new questions of safety and effectiveness.

TABLE 1 COMPARISON OF X-SERIES TO PREDICATE DEVICE

| Specification | X-Series System | X4 System (K120447) |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications for Use | The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals. The X-Series System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability. | The X4 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. The X4 System acquires, records, transmits and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), accelerometer, acoustical and photoplethysmographic signals. The X4 system only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability |
| Patient Population | Ages 6 and older | Adults |
| User | Trained Technician | Trained technician or patient for recording of sleep data. |
| Anatomical Sites | Scalp/Chest | Forehead/Chest |
| Environment of Use | Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting) Clinical Research Environment | Home (data acquisition) Healthcare facility (data acquisition, and analysis.) Clinical Research |

Advanced Brain Monitoring, Inc. X-Series System

| Specification | X-Series System | X4 System (K120447) |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| User Interface | User control, visual indicators | User control, visual and audio indicators |
| Accessories | EEG and ECG electrodes. | EEG and ECG electrodes. |
| Signals Acquired | <ul style="list-style-type: none"> • Scalp EEG • 3-D actigraphy • Optional channels ECG/EEG/EOG/EMG | <ul style="list-style-type: none"> • Scalp EEG • Infra-red (IR) optical signal • Microphone • 3-D actigraphy • Optional channel ECG/EEG/EOG/EMG |
| Acquisition modes | Monitor only | Record or Monitor |
| Power Supply | 2 to 4 240mAH 3.7 Li-Ion batteries | 1 x 600 mAH 3.7V Li-ION battery |
| Battery Charging | Via JED Connector connected to USB port or USB wall charger | Via USB cable connected to USB port or USB wall charger |
| Typical Charging Time | 0.5-5.0 hours | 0.5 – 3.0 hours |
| Operating Time | Monitoring Days after Charge Hours of Use <ul style="list-style-type: none"> • 0-4 Days: 16 to 17 hours 5-10 Days: 14 to 15 hours | Recording Days after Charge Hours of Use <ul style="list-style-type: none"> • 0-4 Days: 13.0 to 15.5 hours • 5-10 Days: 11.5 to 14.8 hours Monitoring Days after Charge Hours of Use <ul style="list-style-type: none"> • 0-4 Days: 6.5 to 7.8 hours 5-10 Days: 6.0 to 7.3 hours |
| Data Storage | Not used. The X-Series system does not include a record mode where data is stored on the recorder. | 2 GB Micro-SD memory card |
| File size per 8 hr recording | 512 MB | 72 MB |
| Dimensions | 5.0" long, 2.25"wide, 1.0" deep | 2.1" long, 1.5"wide, 0.75" deep |
| Weight | 3.9 ounces with two batteries | 2.5 ounces with battery |

Advanced Brain Monitoring, Inc. X-Series System

| Specification | X-Series System | X4 System (K120447) |
|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cleaning | Cleaned and disinfected by rubbing with isopropyl alcohol. | Cleaned and disinfected by rubbing with isopropyl alcohol. |
| Wireless data transfer | Blue tooth 2.0 | Blue tooth 2.0 |
| Maximum Bluetooth wireless transfer distance and rate | Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud | Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud |
| EEG | | |
| Definition | Up to 20 differential or referential channels | 3 or 4 differential or referential channels |
| Signal processing techniques (e.g. filtering, etc.) | Sampling Rate: 256 s/s 0.1 Hz High Pass, hardware 100 Hz Low Pass, hardware | Sampling Rate: 256 s/s 0.1 Hz High Pass, hardware 100 Hz Low Pass, hardware |
| Accuracy, variance and error of measurements, in comparison to standard techniques of measuring identical physiologic variables | Sampling rate: 256Hz Dynamic range: +/- 1000µV Resolution 0.03 µV Peak to peak noise: 3.7 µV (typical) 110dB Common Mode Rejection Ratio (typically) Input Impedance: 100GOhm | Sampling rate: 256Hz Dynamic range: +/- 1000µV Resolution 0.03 µV Peak to peak noise: 3.7 µV (typical) 110dB Common Mode Rejection Ratio (typically) Input Impedance: 100GOhm |

Advanced Brain Monitoring, Inc. X-Series System

| Specification | X-Series System | X4 System (K120447) |
|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Aux – EOG/EMG | | |
| Definition | Up to 4 optional single channel either dual lead electrooculogram (EOG) or electromyogram (EMG) | Optional single channel either dual lead electrooculogram (EOG) or electromyogram (EMG) |
| Signal processing techniques (e.g. filtering, etc.) | Sampling rate 256 Hz 0.1 Hz High Pass, hardware 100 Hz Low Pass, hardware | Sampling rate 256 Hz 0.1 Hz High Pass, hardware 100 Hz Low Pass, hardware |
| Accuracy, variance and error of X4 System measurements, in comparison to standard techniques of measuring identical physiologic variables | ECG: Dynamic range: +/- 2000µV Resolution: 0.06 µV Peak to peak noise: 4.2 µV EMG/EOG: Dynamic range: +/- 1000µV Resolution 0.03 µV Peak to peak noise: 3.7 µV (typical) | EOG: Dynamic range: +/- 2000µV Resolution: 0.06 µV Peak to peak noise: 4.2 µV EMG: Dynamic range: +/- 1000µV Resolution 0.03 µV Peak to peak noise: 3.7 µV (typical) |

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| Specification | X-Series System | X4 System (K120447) |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Aux – ECG | | |
| Definition | Dual lead electrocardiogram Number: Single Channel (optional) Bandwidth: 0.1 to 100Hz –3dB bandwidth Notch Filters: 50, 60Hz, software Common Mode Rejection Ratio: 110dB Input Impedance: 100GOhm Input Range: +/-4mV Accuracy: 16 bits over input range Noise: <5µVpp (typically 4.2µVpp) Maximum Electrode DC Offset: +/-125mV | Dual lead electrocardiogram Number: Single Channel (optional) Bandwidth: 0.1 to 100Hz –3dB bandwidth Notch Filters: 50, 60Hz, software Common Mode Rejection Ratio: 110dB Input Impedance: 100GOhm Input Range: +/-4mV Accuracy: 16 bits over input range Noise: <5µVpp (typically 4.2µVpp) Maximum Electrode DC Offset: +/-125mV |
| Signal processing techniques (e.g. filtering, etc.) | Hardware filtering: 0.1Hz -100Hz bandpass Software Filtering: 50, 60Hz, software | Hardware filtering: 0.1Hz -100Hz bandpass Software Filtering: 50, 60Hz, software |
| Accuracy, variance and error of X4 System measurements, in comparison to standard techniques of measuring identical physiologic variables | Noise: typical 4.2µVpp Dynamic range: +/- 2000µV Resolution: 0.06 µV | Noise: typical 4.2µVpp Dynamic range: +/- 2000µV Resolution: 0.06 µV |

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| Specification | X-Series System | X4 System (K120447) | | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------|-------------|---------------|------------|------------|--------|------------|----------------|------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|----|-------------|-------------|---------------|------------|------------|--------|------------|----------------|------------------------------------|----------------|
| Accelerometer | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Definition | Three channels (X x Y x Z) used by software to measure movement and position Dynamic Range: -180° to 180° | Three channels (X x Y x Z) used by software to measure movement and position Dynamic Range: -180° to 180° | | | | | | | | | | | | | | | | | | | | | | | | |
| Signal processing techniques (e.g. filtering, etc.) | -Sampled 100Hz, downsampled to 10Hz - X x Y x Z @ 10 s/s - Resolution nominal 10 bit at 2g - Actual output range for -90 to 90 degrees is 12 bit | -Sampled 100Hz, downsampled to 10Hz - X x Y x Z @ 10 s/s - Resolution nominal 10 bit at 2g - Actual output range for -90 to 90 degrees is 12 bit | | | | | | | | | | | | | | | | | | | | | | | | |
| Accuracy, variance and error of X4 System measurements, in comparison to standard techniques of measuring identical physiologic variables | Position accuracy typically +/- 3.0 degrees, maximum +/- 5.0 degrees in the +/- 60 degrees range <table border="1"> <thead> <tr> <th>Parameter</th> <th>X-Series</th> </tr> </thead> <tbody> <tr> <td>Sensitivity</td> <td>10 bit / 2g</td> </tr> <tr> <td>Non-linearity</td> <td>+/-0.5 %FS</td> </tr> <tr> <td>Cross-Axis</td> <td>+/-1 %</td> </tr> <tr> <td>Zero-Level</td> <td>+/-0.35-0.4 mg</td> </tr> <tr> <td>Sensitivity change due temperature</td> <td>+/-0.01 LSB/°C</td> </tr> </tbody> </table> | Parameter | X-Series | Sensitivity | 10 bit / 2g | Non-linearity | +/-0.5 %FS | Cross-Axis | +/-1 % | Zero-Level | +/-0.35-0.4 mg | Sensitivity change due temperature | +/-0.01 LSB/°C | Position accuracy typically +/- 3.0 degrees, maximum +/- 5.0 degrees in the +/- 60 degrees range <table border="1"> <thead> <tr> <th>Parameter</th> <th>X4</th> </tr> </thead> <tbody> <tr> <td>Sensitivity</td> <td>10 bit / 2g</td> </tr> <tr> <td>Non-linearity</td> <td>+/-0.5 %FS</td> </tr> <tr> <td>Cross-Axis</td> <td>+/-1 %</td> </tr> <tr> <td>Zero-Level</td> <td>+/-0.35-0.4 mg</td> </tr> <tr> <td>Sensitivity change due temperature</td> <td>+/-0.01 LSB/°C</td> </tr> </tbody> </table> | Parameter | X4 | Sensitivity | 10 bit / 2g | Non-linearity | +/-0.5 %FS | Cross-Axis | +/-1 % | Zero-Level | +/-0.35-0.4 mg | Sensitivity change due temperature | +/-0.01 LSB/°C |
| Parameter | X-Series | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sensitivity | 10 bit / 2g | | | | | | | | | | | | | | | | | | | | | | | | | |
| Non-linearity | +/-0.5 %FS | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cross-Axis | +/-1 % | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zero-Level | +/-0.35-0.4 mg | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sensitivity change due temperature | +/-0.01 LSB/°C | | | | | | | | | | | | | | | | | | | | | | | | | |
| Parameter | X4 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sensitivity | 10 bit / 2g | | | | | | | | | | | | | | | | | | | | | | | | | |
| Non-linearity | +/-0.5 %FS | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cross-Axis | +/-1 % | | | | | | | | | | | | | | | | | | | | | | | | | |
| Zero-Level | +/-0.35-0.4 mg | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sensitivity change due temperature | +/-0.01 LSB/°C | | | | | | | | | | | | | | | | | | | | | | | | | |
| Software | Software presents waveforms | Software presents waveforms | | | | | | | | | | | | | | | | | | | | | | | | |

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the X-Series System was provided as a result of risk management and testing which included electrical and biological safety, performance and software tests. Testing has provided reasonable assurance of safety and effectiveness for the intended use and supports a determination of substantial equivalence.

Bench tests were conducted using an oscilloscope and signal generator to compare performance of the X-Series to the predicate device. These comparison tests confirm the EEG

Advanced Brain Monitoring, Inc. X-Series System

and optional dual-lead (for ECG) analog signals between the X-Series and predicate devices were equivalent. The X-Series and X4 were placed in a jig that held the devices in eight unique angles to confirm that the measures obtained from the 3D actigraphs were equivalent. While the X-Series System is not a cardiac monitor as defined in the scope of ANSI/AAMI EC 13, the standard was referenced and requirements and test methods applicable to the electrocardiogram acquired and displayed by X-Series was applied. These tests demonstrated the equivalence of the X-Series system to the predicate device for EEG, ECG and actigraph performance.

The cleaning and disinfection procedures of the X-Series acquisition device have been validated by testing in accordance with AAMI TIR 12-94 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Manufacturers and AAMI TIR 30: 2003 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices. Acceptance criteria established by Advanced Brain Monitoring and the TIR are $\geq \log 3.0$ reduction in bioburden after cleaning according to the instructions for use. All tests passed and demonstrate that the cleaning methods are appropriate for ensuring the X-Series acquisition device is clean between uses.

Biocompatibility was assessed following FDA Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo)". Per Table 1 of this guidance, the X-Series System is a Surface device with limited contact (Category A, less than 24 hours contact). As such, cytotoxicity, sensitization, and irritation or intracutaneous reactivity tests were selected. Test methods were in compliance with the corresponding standard from the ISO 10993 series for Biological Evaluation of Medical Devices. Test articles were comprised of all patient contacting components of the X-Series System, including the X-Series Strip with disposable foam and synapse cream, X-Series Strap and X-Series enclosure. Results of biocompatibility testing are summarized in table 2 and demonstrate that materials of the device in contact with the patient are biocompatible.

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TABLE 2 BIOCOMPATIBILITY RESULTS

| ISO 10993 Standard | Test | Results | Conclusions |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| ISO 10993-5 | Cytotoxicity Agar Diffusion Test – ISO Direct Contact The test article was applied directly to the surface of the agar of mammalian cell culture (mouse fibroblast L929) and the cells were incubated for 48 ± 2 hours at 37 ± 1°C. The biological reactivity of the cells following the exposure to the test article was visually observed with a microscope, and graded on a scale of 0 to 4. | None of the cultures tested with the test articles showed any reactivity (grade 0). | Non-cytotoxic |
| ISO 10993-10 | Sensitization Buehler Sensitization Test – ISO Direct Contact. The test article, X Series System, was evaluated for its potential to produce skin sensitization reactions following topical application to albino guinea pigs. | Irritation (skin reaction scores) was absent from all the animals (albino guinea pigs). All animals gained weight during the course of the study. No overt signs of toxicity were evident in any of the animals during the course of the study. No skin reaction scores were observed in any of the test animals. No skin reaction scores were evident in the negative control group. The incidence of the responses post-challenge were calculated to be 0% at 24 and 48 hours. | Non-sensitizer |

Advanced Brain Monitoring, Inc. X-Series System

| ISO 10993 Standard | Test | Results | Conclusions |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 10993-10 | Irritation Primary Skin Irritation Test – ISO Direct Contact The X Series System was evaluated for its potential to produce Primary Skin Irritation after a single topical 4 hour application to the skin of New Zealand White rabbits | All test animals gained body weight during the course of the study. No overt signs of toxicity were evident in any of the animals during the course of the study. No signs of erythema or edema were present at the 24, 48, or the 72 hour observation point. None of the control sites of any animal at any of the observation periods showed signs of erythema or edema. The Test Primary Irritation Index (PII) was 0.0. | Non-irritant |

The firmware in the X-Series System and the X-Series Basic software have been thoroughly tested through verification of specifications and validation, including software validation. Software documentation is available per FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document (May 11, 2005). The results of the verification and validation activities that have been performed demonstrate that the software meets requirements for safety, function, and intended use.

Electromagnetic compatibility and electrical safety testing of the X-Series was conducted following recognized standards. Compliance to IEC 60601-2-26:2002 - Particular requirements for the safety of electroencephalographs was also demonstrated. The X-Series System has additionally been tested per IEC 60601-1-11: 2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment to demonstrate operational and mechanical performance is not negatively affected by various mechanical and environmental hazards encountered in the home-use environment. All test results are passing demonstrating the compliance of the X-Series system to FDA recognized standards for electro-medical equipment as defined in Table 3.

The disposable EEG electrodes used with the X-Series System have been tested to demonstrate their electrical performance. While the scope of the standard does not cover EEG electrodes, testing using applicable methods defined in chapter 4 of AAMI/ANSI EC12:2000 (R)2010 Disposable ECG electrodes has been conducted, similarly to other cleared EEG electrodes

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including Model 4310 PSarray2 EEG electrode (K020670). The results demonstrate electrical performance of the EEG electrodes used with the X-Series System is acceptable.

TABLE 3: FDA RECOGNIZED CONSENSUS STANDARDS AND VOLUNTARY STANDARDS THE X-SERIES SYSTEM CONFORMS WITH:

| Standard Number | Standard Title |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IEC 60601-1-1:1988+A1: 1991+A2: 1995 | Medical Electrical Equipment – Part 1: General requirements for safety |
| IEC 60601-1-2: 2007 | Medical Electrical Equipment Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests |
| ISO 10993-1: 2009 | Biological evaluation of medical devices Part 1 |
| IEC 60601-1-11: 2010 | Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| IEC 60601-2-26:2002 | Particular requirements for the safety of electroencephalographs |

SUMMARY OF CLINICAL TESTS:

To provide additional support for use in ages 6 and older, a subset of data from a research study was analyzed to establish use of the X-10 and X-24 headsets to acquire EEG in this patient population. Data from seven children ages 6-8 were compared to data from seven adults. The subjects were set-up by a technician with the X-Series strip appropriate based on their head measurements as described in the labeling. Technicians were able to quickly set-up subjects and resolve any high impedance issues as displayed by the X-Series Software. None of the subjects complained of discomfort or agitation in wearing the strips and the sensors remained in contact with the scalp for the duration of testing. 100% of all EEG sessions contained appropriate EEG recordings that could be further examined in third party software, and when data acquired from children are compared to an equivalent adult population, the data quality were equivalent.

CONCLUSION:

Based on the results of the non-clinical and clinical tests performed, Advanced Brain Monitoring considers the X-Series System to be as safe, as effective, and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 27, 2013

Advanced Brain Monitoring, Inc.
c/o Ms. Adrienne Lenz
W324 S3649 County Road E
Dousman, WI 53118

Re: K131383

Trade/Device Name: X-Series System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OMC
Dated: November 1, 2013
Received: November 5, 2013

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 -Ms. Adrienne Lenz

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
 Acting Director
 Division of Neurological
 and Physical Medicine Devices
 Office of Device Evaluation
 Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131383

Device Name: X-Series System

Indications For Use:

The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals. The X-Series System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S